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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,350	10/11/2001	Martin J. Jacobs	CP215	9510

7590 03/07/2003

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 03/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,350	JACOBS ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/02/02* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,13-15,17-20 and 32-54* is/are rejected.

7)☒ Claim(s) *12, 16 and 21-31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of request for reconsideration filed 12/02/02. No claim was amended.

Claim Rejections - 35 USC § 112

1. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in light of applicants' argument.

Claim Rejections - 35 USC § 102

2. Claims 1-4, 6, 32, 33, 36, 37, 39, 41-44, 47, 48, 51 and rejected under 35 U.S.C. 102(b) as being anticipated by Grebow et al. (US 5,618,845).

Applicants argue that Grebow does not teach particle forming composition according to the definition in the current application, fails to teach particles and that a stable suspension is one that has a mixture of particles that remain intact and dispersed in a liquid medium such that the suspension can be stored and administered in a pharmaceutically acceptable manner.

3. Applicants' arguments filed 12/02/02 have been fully considered but they are not persuasive.

Grebow discloses pharmaceutical composition comprising modafanil particles or modafanil pharmaceutically acceptable salt particles. Grebow's composition is administered as a suspension and because Grebow is silent on whether the suspension is stable or not, Grebow thus teaches stable or non-stable suspension. Applicants claim particles and the prior art teaches particles. Since Grebow discloses a composition comprising modafanil particles that can be administered as a suspension, Grebow teaches all elements of the claims. A particle forming

composition results in particulate composition and the "forming" language does not carry patentable weight. The rejection over Grebow is reiterated below:

Grebow teaches a pharmaceutical composition comprising modafanil particles or modafinil pharmaceutically acceptable salt particles (abstract, column 2, column 3, lines 1-55 and claims 1 and 2) and non-toxic pharmaceutically acceptable carrier (column 4, lines 4-10). Grebow's composition contains an appropriate dosage of between 50 mg and 700 mg of modafinil with a preferred amount of 400 mg (column 4, lines 11-18 and column 10, lines 15-17). The modafinil pharmaceutical composition is administered as a tablet, capsule, powder, pill, liquid, suspension or emulsion; the modafinil composition can also be administered topically via epidermal patch or administered via direct injection (column 10, lines 18-26). Grebow further teaches a method of altering somnolent state, for example, narcolepsy, idiopathic hypersomnia and related sleep disorders by administering to a mammal a pharmaceutical composition comprising an effective amount of modafinil particles; and an effective amount of the pharmaceutical composition is defined as an amount effective for treating the somnolent state (column 3, lines 56-67). In human clinical trials, modafinil is administered to physically and mentally healthy male subjects (column 5, lines 46 to 56).

The composition of Grebow encompasses stable and unstable suspensions because the prior art does not exclude stable suspensions and thus the suspension of Grebow would be inherently stable. Grebow clearly teaches the composition and methods of the application recited in the claims designated above. Therefore, the teachings of Grebow meet the limitations of the claims.

4. Claims 1-4, 6, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51 and 54 rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen et al (US 5,843,347).

Applicants argue that Nguyen does not teach particles and particle forming composition according to the current application.

5. Applicant's arguments filed 12/02/02 have been fully considered but they are not persuasive.

Nguyen discloses modafanil particles in the form of suspension. A particle forming composition results in particulate composition and the forming language does not carry patentable weight. The rejection over Nguyen is reiterated below:

Nguyen teaches a pharmaceutical composition comprising particles or microparticles of active ingredient, physiologically acceptable hydrophilic excipient and water (abstract). The hydrophilic excipient comprises a polymer component and a water-soluble or water dispersible component that acts as a diluent (column 6, lines 1-5). The polymer component is selected from the group consisting of gum Arabic, xanthan gum, gum tragacanth, alginates, pectinates, polyvinylpyrrolidone, **polyethylene glycols**, cellulose, carboxymethyl cellulose, cellulose ethers, carboxymethyl chitin, dextran, chitosan, gelatin, acrylic and methacrylic polymers and copolymers, colloidal silica and mixtures thereof (column 6, lines 11-23). The water-soluble or water dispersible component is selected from the group consisting of lactose, glycocoll, mannitol, glucose, sucrose, maltodextrin, cyclodextrins and derivatives thereof (column 6, lines 44-49). The hydrophilic excipients can also comprise surfactants that are capable of oral administration and the surfactants can be polysorbates, sorbitan esters, fatty glyceride polyethers, lecithins, sodium lauryl sulfate, sodium dioctylsulfosuccinate and mixtures thereof (column 7,

lines 2-7). The process of preparing the modafinil particles involves homogenization of the active ingredient in solution, suspension, or emulsion and freeze drying or lyophilization (column 8, lines 15-24). The active ingredient is selected form the group consisting of paracetamol, probucol, piroxicam, phloroglucinol, tiadenol, flerobuterol, **modafinil**, dexfenfluramine, carbinoxamine maleate, loperamide, lorazepam and mixtures thereof (claim 13). Oral administration is route of administration and route of administration of a composition is not critical in a composition claim.

Nguyen does not exclude stable emulsion and since the prior art is silent on whether the emulsion is stable or unstable, the emulsion of the prior art would necessarily be stable since Nguyen does not teach that the emulsion is unstable and since the emulsion is homogenized and lyophilized. Nguyen does not specifically refer to polyethylene glycol as an organic solvent; but since one of the organic solvents in the application is polyethylene glycol, Nguyen teaches polyethylene glycol organic solvent. The method steps in claims 36 and 37 broadly contacts modafinil particles with water and the composition of Nguyen contains water. Thus Nguyen clearly teaches the composition and the methods of the application in the claims designated above. Therefore, the teachings of Nguyen meet the limitations of the claims.

Claim Rejections - 35 USC § 103

6. Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al (US 5,618,845).

7. Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745).

Applicants state that the rejection should be withdrawn because the references do not teach particle forming compositions and stable suspensions. Applicants further state the cited prior art does not teach the disclosure of the instant application.

8. Applicants' arguments filed 12/02/02 have been fully considered but they are not persuasive.

Regarding the prior art not teaching the disclosure of the instant application, it is respectfully presented that it is the claims of the application that are rejected over the prior art and not the disclosure of the application.

The prior art discloses formulations that are in particulate form and the "forming" language of the claim does not carry patentable weight.

The rejections are reiterated below:

Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grebow et al. (US 5,618,845).

The teachings of Grebow are as described above where it is noted that the appropriate dosage of modafinil is between 50 mg and 700 mg with a preferred amount of 400 mg (column 4, lines 11-18 and column 10, lines 15-17). The dose or amount of modafinil in the composition of the application recited in claims 17, 18, 34 and 35 is encompassed in the amounts disclosed by Grebow. Grebow also teaches administering the prior art composition in clinical trials to mentally and physically healthy male subjects. Orally administering modafinil particles to human subjects (column 5, lines 46-56) would necessarily bring modafinil particles in contact with the aqueous environment in the human subject since human body is mostly water.

Claim 3 of the application does not recite any dose and claims 45 and 46 depend from claim 3. But the dose/amount of modafinil administered to a subject in need thereof in the prior art is effective for treating the somnolent state, and thus modafinil would be present and capable of detection in the blood serum of said subject because, for a drug to be effective, it has to be present in the blood circulation. In the absence of a showing to the contrary, modafinil blood serum levels of 0.05 to 30 μg/ml do not patentably distinguish the invention over the prior art.

Thus, Grebow clearly teaches the composition and methods of the application except that the prior art is silent on the form of the capsule. Since the prior art is silent on the form of the capsule, hard or soft gelatin capsule, the prior art's broad teaching of a capsule encompasses both soft gelatin capsule or hard capsule. The expected result would be a modafinil particle composition encapsulated in soft gelatin capsule or hard capsule. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encapsulate the modafinil particle composition in hard capsule or soft gelatin capsule because the prior art broadly teaches capsules and capsules can either be soft or hard. One having ordinary skill in the art would have been motivated to encapsulate the composition of the prior art in soft gelatin capsules or hard capsules since the prior art does not exclude either form of the capsule.

Claims 8-10, 13, 17-20, 34, 35, 38 and 40-46 rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,843,347) in view of Lafon (US 5,180,745).

Nguyen is discussed above. However, Nguyen fails to teach administering the composition to a subject in need thereof to treat any of the conditions recited in claim 44.

But, Lafon teaches a method of treating Parkinson's disease where the method comprises administering to a patient in need thereof a therapeutically effective amount of modafinil (claim

1) . For modafinil to be effective in treating Parkinson's disease, the modafinil administered must be carried by the blood to the target areas, which implies that the level of modafinil in the blood serum is effective for treating the Parkinson's disease. In the absence of a showing to the contrary, modafinil blood serum levels of 0.05 to 30 μg/ml do not patentably distinguish the invention over the prior art.

Parkinson's disease is one of the conditions recited in claim 44. Lafon teaches that the dose administered to humans varies form 50 mg to 1000 mg (column 1, lines 33 and 34). The dose of 200 mg and 100 mg recited in claims 34 and 35 lie within the disclosed range of 50-1000 mg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to orally administer the composition of Nguyen to treat Parkinson's disease because Lafon administers modafinil to treat the disease. One having ordinary skill in the art would have been motivated to treat Parkinson's disease by administering to a subject in need of treatment the composition of Nguyen where the modafinil dose is 50 mg to 1000mg because Lafon teaches that the dose of modafinil administered to humans varies from 50 mg to 1000 mg.

Double Patenting

9. Claims 1, 3-5, 14, 15, 32-34 and 35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, 8, 10-13 and 26-29 of copending Application No. 09/974,473.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner respectfully thanks applicants for indicating that the provisional obviousness type double patenting will be addressed when application serial number 09/974,473 becomes a patent.

Claims 12, 16 and 21-31 remain objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims because the prior art does not teach a second surfactant that is a polyoxyethylene sorbitan fatty acid ester.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 3, 2003

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615